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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,177	11/17/2003	Roisin A. Armstrong	1/1345	4041

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,177	ARMSTRONG ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11-19* is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-10, 20-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending.

Election/Restrictions

Claims 11-19 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election with traverse of invention Group I, drawn to a composition claims 1-10, 20-34 in reply filed on 04/12/2007 is acknowledged. The traversal is on-the grounds(s) that carrying out the method with a distinct compound, i.e., slabutamol, would necessarily result in a materially different process because salbutamol is a materially different compound. This argument has been considered, but not found persuasive. Inventions I and II are related as product and process of using the product. The inventions can be shown to be distinct if the process for using the product as claimed can be practiced with another materially different product. (MPEP 806.05(h)). In the instant case COPD can be treated by administering salbutamol. Further, a search for the invention of the 2 groups would not be coextensive because a search indicating the process is novel or unobvious would not extend to a holding that the product itself is novel or unobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious. Therefore, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10, 20-34 are examined herein as they read on the elected invention.

Claim Objections

Claims 5, and 33 are objected to because of the following informalities:

In claim 5, lines 3, and 4, the PDE4 inhibitor should be triazolo[4,3-α]pyridine, and not triazolo[4,3-a]pyridine.

In claim 33, the word "from" is missing after the word selected.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, and 20-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "selected from the group consisting of tiotropium, and pharmaceutically acceptable salts, isomers, isotopes, polymorphs, hydrates and solvates thereof" in claim 1, renders the claims indefinite as it is not clear whether the composition comprises a) tiotropium, and b) a pharmaceutically acceptable salt or isomer or isotope or polymorph or hydrate or solvate thereof or if the composition comprises just one of the compound i.e for example tiotropium salt. Further, note that the Markush recitation should be in alternative form and singular.

Written Description:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9, 20-23, 29-30, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims recite hydrates and solvates of tiotropium. Applicant's specification does not provide support for the recitation "hydrates and solvates of tiotropium". Accordingly, the claimed subject matter has not been described in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed were actually in possession of such as compound having the dual activity, and thus the claim fails to meet the written description requirement under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, and 20-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duplantier et al. (US 6,004,974, PTO-1449), in view of Barnes (Am J Respir Crit Care Med, Vol 160, ppS72-S79, 1999, PTO-1449).

Duplantier et al. disclose composition comprising a PDE4 inhibitor, a compound of formula I which read on the instant PDE4 inhibitors of Formula (1.1.1) in a carrier. The compositions therein are useful in treating asthma, chronic obstructive airway diseases, and other inflammatory diseases. See abstract; column 1- column 4. It is also taught that the compositions therein can be administered in a form suitable for administration by inhalation. See column 12, lines 1-5.

Duplantier et al. do not teach anti-cholinergic agent, tiotropium bromide in the composition therein.

Duplantier et al. do not specifically teach the compositions therein in the form of an aerosol or dry powder inhaler as in claim 21, and claim 29.

Barnes teaches that anticholinergic bronchodilator, tiotropium bromide in the form of dry powder inhaler is in Phase III clinical trials for treating chronic obstructive pulmonary disease (COPD). It is also taught that PDE4 inhibitors are effective in treating COPD. See abstract; page S72.; page S76. Barnes teaches that bronchodilators are given via inhalers, either as metered dose inhalers or dry powder inhalers.

It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Duplantier et al. and Barnes, the instant claims contain two compositions used for treatment of chronic obstructive pulmonary disease. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the compositions taught by Duplantier et al. in the form of dry powder inhaler because Barnes teaches that the compositions for treating chronic obstructive pulmonary diseases are employed in the form of inhalable dry powder in a metered dose inhaler or dry powder inhaler.

Further, the patient pack is deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication and given that-compounds are taught to be effective for treating COPD. Furthermore, one of ordinary skill in the art would have been motivated to prepare a pack comprising the same composition because the preparation of a pack comprising a pharmaceutical composition is considered well in the competence level of an ordinary skilled artisan in the pharmaceutical science, involving merely routine skill in the art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER